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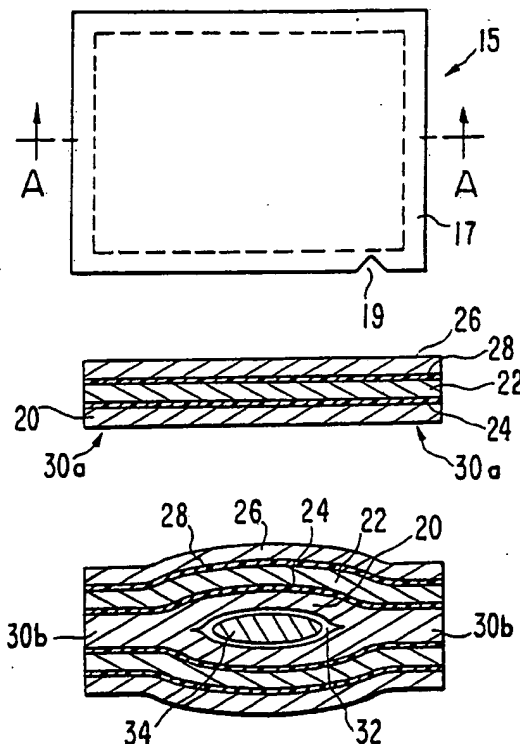
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- gum

(54) Title: NICOTINE PACKAGING MATERIALS**(57) Abstract**

A nicotine containment pouch (15) is formed from laminates comprising a nicotine barrier layer (20) and a nicotine degradation agent barrier layer (22). The preferred nicotine barrier layer comprises a nitrile rubber modified acrylonitrile-methyl acrylate copolymer formed by the graft copolymerization of 75 pbw acrylonitrile, and 25 pbw methyl acrylate in the presence of about 10 pbw of a butadiene-acrylonitrile copolymer containing about 70 % by weight of polymer units derived from butadiene. The preferred nicotine degradation agent barrier layer is aluminum. The exterior surface of the pouch is optionally covered by a protective layer (26) of paper stock or polyethylene terephthalate. The nicotine barrier layer is bonded to itself about the periphery of a nicotine containing body (34) within the pouch.



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NICOTINE PACKAGING MATERIALS**Technical Field**

The invention herein pertains to materials and methods for the
5 manufacture of nicotine storage pouches.

Background Art

Nicotine containing products are known to the art for numerous
purposes including swine and food additives, U.S. Patent 3,252,802;
dosage forms for the treatment of mental conditions, U.S. Patent
10 3,870,794 and 4,680,172; pain, U.S. Patent 4,665,069; hypertension,
U.S. Patent 4,748,181; and nicotine addiction, U.S. Patents
3,877,468, 3,845,217, 4,597,961, 4,715,387, 4,758,434, 4,839,174 and
4,943,435 for example.

Nicotine base, however, is a reactive species which degrades
15 in the presence of oxygen or light and is highly hygroscopic.
Nicotine base also causes the solvation of adhesives typically used
in the manufacturer of pouch stock which prevents their effective
use when exposed to nicotine.

The problem of providing containment for products containing
20 nicotine base is described in patents 4,839,174 and 4,943,435 and
has heretofore found no simple solution. For example, transdermal
systems for the delivery of nicotine are disclosed in U.S. patents
4,781,924 and 4,837,027 and Australian Patent Application Au-A-
81454/87. All of the above noted U.S. patents are incorporated
25 herein by reference. In those systems nicotine precursors instead
of nicotine base are in the devices prior to use and the precursors
are converted to the highly reactive nicotine immediately prior to
or after application to the skin thereby avoiding the problems
associated with the long term storage of nicotine. A commercially
30 available nicotine releasing chewing gum is available as Nicorette®
(Lakeside Pharmaceuticals). This dosage form is packaged in a foil-
plastic blister pouch, however, prior to use, the nicotine is
chemically bound within a polymeric material in the form of nicotine
polacrilex.

There is a need therefore, to provide a container in the form of pouch or blister pack, for example, which can hold one or more nicotine-containing devices in a stable manner for extended periods of time. To function properly such a container should be inert to nicotine; that is, it would not cause degradation of nicotine base, or be degraded by nicotine. The container should also act as a barrier to nicotine and to agents which are detrimental to the stability of nicotine base such as air, moisture and light.

Air (oxygen) and light both act to degrade nicotine base. Since nicotine is strongly hygroscopic, nicotine tends to absorb water in liquid or vapor form which would cause a change in the concentration or thermodynamic activity of the nicotine in the product and thereby effect its performance.

Materials which were known, or could be reasonably expected, to provide a barrier to nicotine and provide protection from nicotine degradation agents include metal foils such as aluminum foil, polyesters such as polyethylene terephthalate (PET), and fluorinated polymers such as poly(tetrafluorethylene) (PTFE). However, these materials require the use of an adhesive to bond opposing surfaces and we have found that the adhesive itself can provide a path for migration of nicotine out of the package and/or migration of degradable agents into the package. We have also found that many self-sealable pouching materials of the prior art such as polyvinyl fluoride (PVF), polyvinylidene fluoride (PVDF), chlorotrifluoroethylene (CTFE), low density polyethylene (LDPE), and high density polyethylene (HDPE) do not provide an effective barrier for nicotine or its degradation agent.

As a result, prior to our invention, a nicotine containing pouch or package capable of enclosing nicotine in a stable manner, over a long period of time, was not available.

It is therefore an object of this invention to provide a container for nicotine base or for products containing nicotine base.

It is another object of the invention to provide a pouching material which acts as a barrier to nicotine and nicotine

degradation agents such as air (oxygen), water in liquid or vapor form, and light.

It is yet another object of the invention to provide a pouch which is suitable for long-term containment of nicotine-containing transdermal delivery devices.

Brief Description of Drawings

Figure 1 shows a top view of a pouch of this invention.

Figure 2 shows a cross-sectional representation of a laminate useful to form a pouch of Figures 1.

Figure 3 shows a cross section of the pouch of Figure 1 taken through line A-A. The pouch has been formed of the laminate of Figure 2.

Figures 4, 6, 8 and 10 show representations of the laminates used to form the pouches of Figures 5, 7, 9 and 11, respectively.

Figures 7 through 11 show views of alternate embodiments of a pouch such as that shown in Figure 1.

Figure 12 shows comparative nicotine transmission data for various barrier materials.

Brief Description of Invention

The invention herein pertains to methods and materials for producing a package for enclosing a nicotine containing product in a stable manner over an extended period of time of at least one year and preferably at least two years.

Laminates comprising a nicotine barrier layer and a nicotine degradation agent barrier layer are disclosed. The nicotine barrier layer of this invention comprises a nitrile rubber modified acrylonitrile-methyl acrylate copolymer (hereafter "AN-MA/B"). The preferred material comprises the material produced by the graft copolymerization of about 73-77 parts by weight (pbw) acrylonitrile and about 23-27 pbw of methyl acrylate in the presence of about 8-10 pbw of butadiene-acrylonitrile copolymer containing approximately 70 wt % of polymer units derived from butadiene (hereafter "73-77 AN-MA/B"). An especially preferred nicotine barrier material comprises the graft copolymer of 75 pbw acrylonitrile, and 25 pbw methyl acrylate in the presence of 10 pbw of the butadiene-acrylonitrile

copolymer (hereafter "75AN-MA/B"). A preferred nicotine degradation agent barrier layer is a metal film, preferably aluminum. A preferred embodiment of the pouch stock of this invention comprises a laminate of a layer of 75AN-MA/B adhered to a layer of aluminum foil, which may optionally be provided with an external protective layer formed from paper, polymeric materials or the like.

A method for the production of the pouches of this invention comprises: (a) providing a laminate including a self-sealing nicotine barrier layer and a nicotine degradation agent barrier layer; (b) depositing a source of nicotine on said laminate; (c) enclosing said source within said laminate; and (d) sealing the self-sealing nicotine barrier layer.

Disclosure of Invention

Nicotine (beta-pyridyl-alpha-N-methylpyrrolidine) is a colorless liquid alkaloid derived from tobacco or by synthetic manufacture. It is a strongly alkaline, hygroscopic liquid which degrades upon exposure to air (oxygen) or light, the principal degradation products being cotinine and the cis and trans N-oxides of nicotine.

As used herein, the term "pouch" refers to a pouch package, blister pack or other container for nicotine which is sealed on at least one side. The sealed pouches of this invention can comprise, for example, two sheets of the above described laminates which have been joined along all edges; a single sheet of the laminate which has been folded and sealed along all edges or along all non-fold edges; a bag or pocket which is sealed along one or more edges; and the like.

"Self-sealing" refers to the ability of a material to form a stable bond between one face of the material and another face of the same material. Self-sealing is accomplished, for example, by heat (thermal bar) sealing, impulse, radio frequency, ultrasonic sealing, and the like.

As used herein, a "nicotine barrier" is a material that permits, at ambient conditions (30°C or below), less than 1% by weight of the nicotine content of the packaged product to migrate

over a period of six months and more preferably less than 0.5% and most preferably substantially no nicotine migration. The nicotine barrier material is also inert with respect to nicotine, i.e., nicotine does not act as a solvent or plasticizer for the barrier material, does not cause stress cracking, crazing or otherwise adversely affect the physical characteristics of the barrier material and the barrier material does not cause the nicotine to degrade.

As used herein, "nicotine degradation agents" refer to air (particularly oxygen), water in liquid or vapor form, and light. A "nicotine degradation agent barrier" is a barrier which is opaque and substantially impermeable to nicotine degradation agents.

"Nicotine containment" refers to the long-term, at least six months at ambient conditions, storage of nicotine base especially as embodied in a nicotine device, without significant migration of the nicotine out of the storage container, and without significant degradation of the nicotine by oxygen, water, or light.

As used herein, significant degradation of the nicotine is considered to have occurred if the nicotine component of the device contains 3 wt% or more of total impurities, including water and nicotine degradation products such as cotinine and the cis and trans N-oxides of nicotine. It is preferred to maintain the total impurity content below about 1 wt% of the nicotine content of the nicotine device and most preferably as close to zero as possible.

The term, "nicotine device" as used herein, refers to a source of nicotine, typically an object such as, for example, a nicotine dosage form for use in smoking cessation which can be in the form of chewing gum, lozenge, tablet, suppository, transdermal delivery devices and the like and which include nicotine base.

The preferred pouching material is a laminate comprising a self-sealing nicotine barrier and a nicotine degradation agent barrier. The combination of self-sealing nicotine barrier and nicotine degradation agent barrier provides for simultaneous containment of the nicotine and protection of the nicotine from degradation.

The preferred self-sealing nicotine barrier material is a nitrile rubber modified acrylonitrile-methyl acrylate copolymer (AN-MA/B). Preferably the self-sealing nicotine barrier material comprises the AN-MA/PB material described above and the especially preferred nicotine barrier material comprises the 75AN-MA/B material described above. These materials are disclosed, for example, in U.S. Patent 3,426,102 which is incorporated herein by reference, and are commercially available as BAREX® resins in bulk and film form from numerous sources including Sohio Chemical Company, BP Chemicals International, Greenway Industries Corp., West Paterson, New Jersey, and Toyomenka (America) Inc., New York, New York, for example.

Various grades of 73-77 AN-MA/B are available, for example, BAREX 210, 214 and 218 of which BAREX 210 corresponds to the preferred 75AN-MA/B material.

The thickness of the AN-MA/B film used according to this invention will generally be from about 0.8 mil (20μ) or less to about 2.5 mil (65μ) or greater, and is preferably from about 1.0 mil (25μ) to about 2.0 mil (50μ). Thinner films can be used as long as the finished pouch is well-sealed and provides the requisite impermeability to the nicotine. Thicker films can be used as long as the sealing properties are not adversely affected, i.e., as long as the thicker films can be sealed properly with the heat-sealing equipment used. Films should not be so thick that the self-sealed portions (which are unprotected by a nicotine degradation agent barrier) provide a path for light, oxygen and/or water migration into the pouch.

While we have found AN-MA/B materials to be excellent nicotine barriers; they do not provide sufficient protection from nicotine degradation agents to function as a nicotine degradation agent barriers for the long-term containment of nicotine devices.

The transmission of oxygen by the preferred 75AN-MA/B material is reported to be as high as $0.8 \text{ cm}^3 \text{ mil}/100 \text{ in}^2 \cdot 24 \text{ hr.}, \text{ atm.}$ ($0.3 \text{ cm}^3 \cdot \text{mm}/\text{m}^2, 24 \text{ hr.}$) The water vapor transmission rate of this material is reported to be as high as $5.0 \text{ g mil}/100 \text{ in}^2, 24 \text{ hr.}$ ($2.0 \text{ g mm}/\text{m}^2, 24 \text{ hr.}$) at 100°F (38°C) and 100% relative humidity.

We have tested the preferred 75AN-MA/B material at 30°C, and at 10% and 90% relative humidity to determine the water uptake. After four hours the film at 10% RH had absorbed .32 wt.% water. After four hours the film at 90% RH had absorbed 2.4 wt.% water. These levels
5 of oxygen transmission and water absorption render the preferred AN-MA/B material unsuitable, by itself, as a nicotine containment material.

AN-MA/B materials are available in untinted (light straw) and blue-tinted transparent film form and these materials do not provide
10 sufficient light protection to prevent nicotine decomposition by light.

To provide an effective nicotine containment means according to our invention, the AN-MA/B nicotine barrier must be combined with a nicotine degradation agent barrier, which acts to inhibit the
15 transmission of oxygen, water in liquid and vapor form, and light. The preferred nicotine degradation agent barrier is a metal film bonded to the 73-77 AN-MA/B nicotine barrier. Aluminum foil is preferred because of cost and availability.

It is also possible to vapor deposit aluminum or other metals
20 directly onto AN-MA/B films and such materials could be used instead of metal foil provided the metal film so produced is sufficiently free of pin holes and irregularities to have the desired degradation agent barrier properties. If vapor deposited films are used, they offer the advantage of eliminating the adhesive or other bonding
25 agent used to form the AN-MA/B aluminum foil laminate.

The thickness of the aluminum film is generally from less than about 0.35 mil (9μ) to about 1 mil (25μ) or greater. Films less than 0.35 mil (9μ) can be used when the film is of sufficient
30 quality that irregularities and holes are minimized. Films thicker than 1 mil can be used, but tend to make the lamination process more difficult and the finished package somewhat stiffer.

In a preferred embodiment, the AN-MA/B nicotine barrier and an aluminum foil nicotine degradation agent barrier are bonded together to form a laminate. The laminate can be formed using a urethane
35 adhesive such as AdcoteTM 548 (Morton Chemical Co., Woodstock,

Illinois) to bond the 73-77 AN-MA/B to aluminum foil.

It is also desirable to provide the laminate of this invention with an additional external protective lamina. This lamina is preferably formed from paper or a printable polymer such as polyethylene terephthalate (PET). Use of PET which is tear resistant offers the additional advantage of making the pouch more "child proof." This outer layer provides the finished pouch with a protective covering which prevents damage to the other layers, is attractive, and is a good substrate for printing. Thickness is not critical as long as it does not interfere with the sealing process, and 35# kraft paper, 35# clay coat paper and 48 gauge (12 μ) PET film are suitable. The protective layer, if present, can be adhered to the degradation agent lamina layer with any suitable adhesive such as polyethylene ethylene or an acrylic acetate (EAA) adhesive or to the nicotine barrier layer with an EAA adhesive, for example.

The nicotine containment pouches can be in any convenient form that permits the effective closure of the pouching materials and the formation of substantially complete nicotine and nicotine degradation agent barriers. The perimeter of the pouches can be, for example, oval, circular, triangular, irregularly shaped, square, rectangular, and the like. For ease of manufacturing when the pouch is heat sealed, a square or rectangular shape is preferred.

The nicotine containment laminate can be self-sealed to form a nicotine containment pouch using any appropriate methods. 73-77 AN-MA/B film, for example, can be sealed using a variety of methods including heat (thermal bar) sealing, impulse sealing, radio frequency sealing, ultrasonic sealing, and the like.

Referring now to the drawings, FIGURE 1 is a top view of a pouch 15 according to this invention. The edges 17 are self-sealed to form an enclosure which is substantially impermeable to nicotine and to nicotine degradation agents. A simple cut, or a notch 19 can be placed in the sealed edge area 17 to assist in opening the pouch.

FIGURE 2 is a cross-sectional view of a self-sealing laminate which is useful for producing pouches of this invention. The self-sealing nicotine barrier layer 20 is adhered to the nicotine

degradation agent barrier layer 22 by an adhesive layer 24. A protective coating layer 26 is adhered to the nicotine degradation agent barrier layer 22 by adhesive layer 28. The laminate can be self-sealed, for example, at edges 30a.

5 FIGURE 3 is a cross-sectional representation of the preferred embodiment of the pouch 14 of FIGURE 1, taken across line A-A. It is formed from the laminate of FIGURE 2. The self-sealing nicotine barrier layer 20 has been sealed at the edges 30b and forms an enclosure 32. Within the enclosure 32 is a nicotine device 34 such as a transdermal delivery device for the transport of nicotine base across the skin.

10 FIGURE 4 is a cross-sectional view of a an alternate self-sealing laminate which is useful for producing pouches of this invention. The self-sealing nicotine barrier layer 40 is adhered to the nicotine degradation agent barrier layer 42 by an adhesive layer 44. The laminate has self-sealable edges 50a.

15 FIGURE 5 is an alternate cross-sectional representation of the pouch 14 of FIGURE 1, taken across line A-A. It is formed from the laminate of FIGURE 4. The self-sealing nicotine barrier layer 40 has been sealed at the edges 50b and forms an enclosure 52. Within the enclosure 52 is a nicotine device 54.

20 FIGURE 6 is a cross-sectional view of a an alternate self-sealing laminate. The self-sealing nicotine barrier layer 60 is adhered to the nicotine degradation agent barrier layer 62 by an adhesive layer 64. The nicotine degradation agent barrier layer 62 and adhesive layer 64 do not completely cover the nicotine barrier layer 60 leaving edges 70a uncoated and available for self-sealing.

25 FIGURE 7 is a cross-sectional representation of the pouch 15 of FIGURE 1, taken across line A-A, formed from the laminate of FIGURE 6. The self-sealing nicotine barrier layer 60 has been sealed at the edges 70b. The nicotine degradation agent barrier 62 and adhesive layer 64 are interior to the nicotine barrier layer 60, and, together with the nicotine barrier layer 60, form an enclosure 72. Within the enclosure 72 is a nicotine device 74.

FIGURE 8 is a cross-sectional view of a an alternate self-sealing laminate. The self-sealing nicotine barrier layer 80 has been metallized and the nicotine degradation agent barrier layer 82 comprises a metallic film. The laminate has self-sealing edges 90a.

5 FIGURE 9 is a cross-sectional representation of the pouch 15 of FIGURE 1, taken across line A-A which has been formed from the laminate of FIGURE 8. The self-sealing nicotine barrier layer 80 has been sealed at the edges 90b and forms an enclosure 92. Within the enclosure 92 is a nicotine device 94.

10 FIGURE 10 is a cross-sectional view of a self-sealing laminate. The self-sealing nicotine barrier layer 100 has been selectively metallized to produce a nicotine degradation agent barrier layer 102 which does not obstruct the edges 110a of the nicotine barrier layer 100.

15 FIGURE 11 is a cross-sectional representation of the pouch 15 of FIGURE 1, taken across line A-A, formed from the laminate of FIGURE 10. The self-sealing nicotine barrier layer 100 has been sealed at the edges 110b. The nicotine degradation agent barrier 102 is interior to the nicotine barrier layer 100, and, together
20 with the nicotine barrier layer 100, forms an enclosure 112. Within the enclosure 112 is a nicotine device 114.

 The following examples are illustrative of the present invention. They are not to be construed as limitations of the scope of the invention. Variations and equivalents of these examples will
25 be readily apparent to one skilled in the art in light of the present disclosure, and the claims herein. All percentages are weight percentages, and all temperatures are in degrees Celsius, unless otherwise noted.

Example 1

30 5.0 ml nicotine base was heat-sealed within a pouch made of a 2 mil (50 μ) film of the preferred 75AN-MA/B material described above. The outside dimensions of the pouch were approximately 3 cm by 6 cm. The pouch was placed in a bottle with 50 g. distilled water. The bottle was maintained at 51°C in a water bath.

The above procedure was repeated, substituting for the 75AN-MA/B films of the following materials: a 2 mil film of TEDLAR polyvinyl fluoride (PVF) available from duPont de Nemours, Wilmington, Delaware; a 3 mil film of KYNAR polyvinylidene fluoride (PVDF), Westlake Plastics Co., Lenni, Pennsylvania; a 2 mil film of high density polyethylene (HDPE) core material, stripped pouch stock, laminated with 1 mil aluminum foil and 35# Kraft paper (lamine provided by Richmond Technology, Redlands, California.) Nicotine migration through the pouches was determined, and is shown in Figure 12. All materials other than the AN-MA/B material showed excessive nicotine migration.

Example 2

Films of various ACLAR chlorotrifluoroethylene polymers (CTFE), available from Allied Chemical Corp., Morristown, New Jersey, were exposed to nicotine in standard diffusion cells in an attempt to determine the permeability of such films to nicotine. 1.5 mil (38 μ) and 3 mil (76 μ) films of the copolymer ACLARTM 22A, and 1 mil (25 μ) film of the tripolymer ACLA[®] 33C were tested. The films all suffered failure due to nicotine induced stress cracks before the tests could be completed.

Example 3

A 1.5 mil (38 μ) thickness of the preferred 75AN-MA/B material (Greenway Industries Corp.) was laminated with 1 mil (25 μ) aluminum foil using an Adcote 548 urethane adhesive with Catalyst F available from Morton Chemical Co., Woodstock, Illinois. The aluminum foil was then bonded to a 35# Kraft paper using 7# low density polyethylene (LDPE) to produce a laminate. The laminate was passed through a Circle Design (2-up) packager (Paxall Circle Design Machinery) having, at each sealing station, a metal heat bar at 425°F and an opposed rubber heat bar at 300°F. Sufficient pressure was applied to provide a good seal. A transdermal nicotine delivery device according to copending patent application serial number 06/906,730 was enclosed within the pouch. The nicotine device suffered no significant loss or degradation of its nicotine content when stored at 30°C for 18 months.

Example 4

A 1.5 mil (38μ) thickness of the AN-MA/B material of Example 3 was laminated with 0.35 mil (9μ) aluminum foil using the adhesive of Example 3. The aluminum foil was then bonded to a 35# clay coat paper using 7# LDPE, to produce a laminate. The laminate was formed into a nicotine device containing pouch as in Example 3 above. The nicotine device suffered no significant loss or degradation of its nicotine content when stored at 30°C for 18 months.

Example 5

A 2.5 mil (63μ) thickness of the AN-MA/B material of Example 3 was laminated with 0.35 mil (9μ) aluminum foil and 35# clay coat paper as described in Example 4. The laminate was formed into a nicotine device containing pouch as above. The nicotine device suffered no significant loss or degradation of its nicotine content when stored at 30°C for 18 months.

Example 6

A laminate of 30μ of the AN-MA/B material of Example 3, 3μ urethane adhesive, 9μ aluminum, 20μ low density polyethylene adhesive and 58μ 35# clay coat paper was manufactured by Tomapoly Company, Ltd., Tokyo, Japan. When fabricated into nicotine containment pouches as described herein the pouches will be capable of stably containing nicotine for extended periods of time.

Example 7

A pouch similar to that of Example 6 is formed by substituting 48 gauge (12μ) printable PET for the paper and 10 pound (17μ) EAA adhesive for the LDPE adhesive. The pouch is tear resistant and capable of stably containing nicotine for extended periods of time.

While the present invention has been described with respect to certain embodiments thereof, it should not be construed as limited thereto. It will be apparent to one skilled in the art that variations, modifications and substitutions can be made without departing from the scope of our invention, which is limited only by the following claims.

WE CLAIM:

1. A laminate for use in producing nicotine containment pouch comprising:
 - a) a nicotine barrier layer comprising a nitrile rubber modified acrylonitrile-methyl acrylate copolymer; and
 - b) a nicotine degradation agent barrier layer.
2. A laminate according to Claim 1 wherein the nicotine barrier layer comprises a copolymer formed from about 73-77 pbw acrylonitrile copolymerized with about 23-27 pbw methyl acrylate in the presence of about 8-10 pbw butadiene acrylonitrile copolymer containing about 70% by weight of polymer units derived from butadiene.
3. A laminate according to Claim 2 wherein the nicotine barrier comprises about 75 pbw acrylonitrile and 25 pbw methyl acrylate copolymerized in the presence of about 10 parts by weight of the butadiene/acrylonitrile copolymer.
4. A laminate according to Claim 1, 2 or 3 wherein the nicotine degradation agent barrier layer is a metal film.
5. A laminate according to Claim 4 wherein the nicotine degradation agent barrier layer is aluminum.
6. A laminate according to Claim 5 further comprising a protective layer forming one surface of said laminate.
7. The laminate of claim 6 wherein said protective layer is formed from a material selected from the group consisting of paper and polyethylene terephthalate.
8. A nicotine containment pouch comprising:
 - a) a nitrile rubber modified acrylonitrile-methyl acrylate copolymer nicotine barrier having a volume enclosed therein;

- b) a nicotine degradation agent barrier disposed to prevent entry of nicotine degradation agents into said volume; and
- c) nicotine base within said volume.

5 9. A pouch according to Claim 8 wherein the nicotine barrier layer comprises a copolymer formed from about 73-77 pbw acrylonitrile copolymerized with 23-27 pbw methyl acrylate in the presence of 8-10 pbw butadiene acrylonitrile copolymer containing about 70% by weight of polymer units derived from butadiene.

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10. A pouch according to Claim 8 wherein the nicotine barrier comprises about 75 pbw acrylonitrile and a copolymer formed from 25 pbw methyl acrylate in the presence of about 10 pbw of the butadiene/acrylonitrile copolymer.

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11. A pouch according to Claim 8, 9 or 10 wherein the nicotine degradation agent barrier layer is aluminum.

20

12. A pouch according to Claim 11 further comprising a protective layer forming the external surface of said pouch.

25

13. The pouch of claim 12 wherein said protective layer is formed from a material selected from the group consisting of paper and polyethylene terephthalate.

14. A pouch according to Claim 12 wherein said nicotine degradation agent barrier layer is disposed on the external surface of said nicotine barrier.

30

15. A pouch according to Claim 12 wherein said nicotine degradation agent barrier layer is disposed on the internal surface of said nicotine barrier.

16. A pouch enclosing a nicotine device, the walls of the pouch comprising, sequentially:

- 5 (a) a self-sealed nicotine barrier defining a volume therein and comprising the copolymer formed from about 75 pbw acrylonitrile, and about 25 pbw methyl acrylate copolymerized in the presence of 10 pbw butadiene/acrylonitrile copolymer containing about 70% polymer units derived from butadiene.
- 10 (b) a first adhesive layer on the external surface of said nicotine barrier;
- (c) a nicotine degradation agent barrier layer comprising aluminum foil on said adhesive layer;
- (d) a second adhesive layer on the external surface of said aluminum;
- 15 (e) an external protective layer on said second adhesive layer; and
- (f) a source of nicotine in said volume.

17. A pouch according to Claim 16 wherein the walls of said
20 nicotine barrier are from about 0.8 mil (20 μ) to about 2.5 mil (64 μ) thick.

18. A pouch according to Claim 17 wherein the nicotine degradation agent barrier layer comprises aluminum foil having a thickness of
25 from about 0.35 mil (9 μ) to about 1 mil (25 μ).

19. A pouch according to claim 16 wherein the protective layer is formed from a material selected from the group consisting of paper and polyethylene terephthalate.

30

20. A method of forming a pouch containing nicotine base comprising:

- 35 (a) providing a laminate comprising (i) a self-sealing nitrile rubber modified acrylonitrile-methyl acrylate copolymer nicotine barrier layer and (ii) a nicotine

degradation agent barrier layer;

- (b) applying a source of nicotine to said laminate; and
- (c) enclosing the source of nicotine in said laminate by bonding the self-sealing nitrile rubber to itself about the periphery of said source.

5

21. A method according to Claim 20 wherein the nicotine barrier layer comprises a copolymer of about 73-77 pbw acrylonitrile and about 23-27 pbw methyl acrylate copolymerized in the presence of about 10 pbw butadiene acrylonitrile copolymer containing approximately 70% of polymer units derived from butadiene.

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22. The method of Claim 20 wherein said nicotine barrier layer is formed from about 75 pbw acrylonitrile and 25 pbw methyl acrylate copolymerized in the presence of about 10 pbw of the butadiene.

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23. A method according to Claim 20, 21 or 22 wherein the nicotine degradation agent barrier layer is aluminum.

20 24. A method according to Claim 23 wherein the laminate of step (a) further comprises an adhesive layer between said nicotine barrier layer and said nicotine degradation agent barrier layer.

25 25. A method according to Claim 24 wherein the laminate of step (a) further comprises, a protective layer bonded to said laminate and disposed to form the external surface of the pouch.

26. A method according to claim 24 wherein the protective layer is formed from a material selected from the group consisting of paper and polyethylene terephthalate.

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FIG. 1

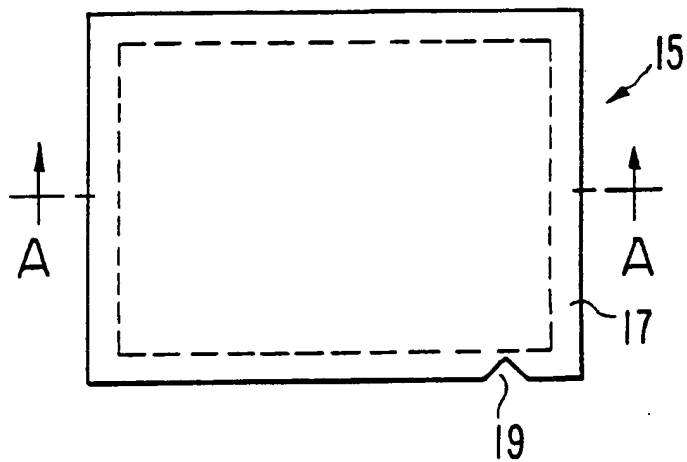


FIG. 2

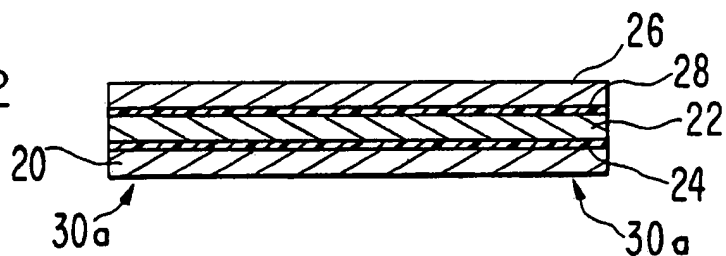


FIG. 3

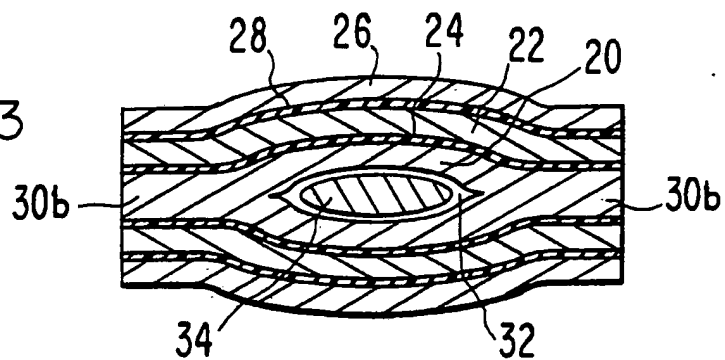


FIG. 4

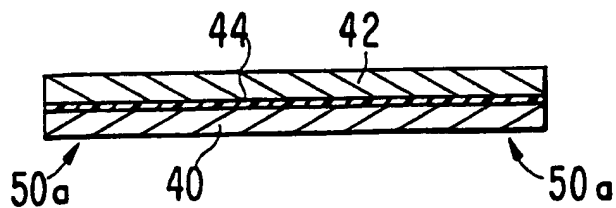
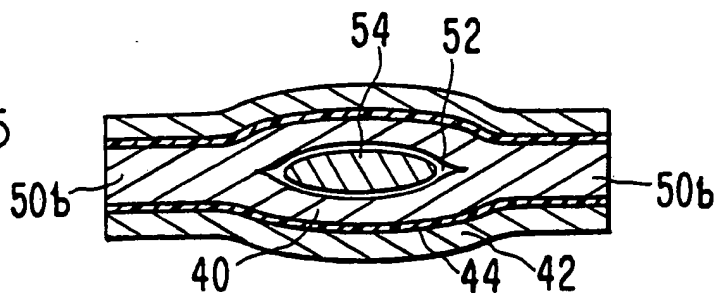


FIG. 5



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FIG. 6

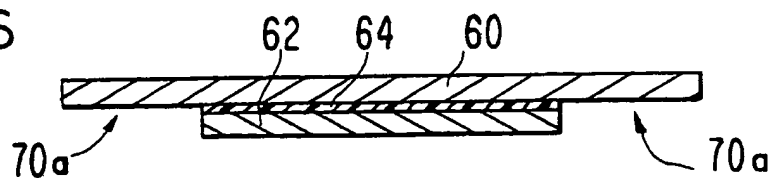


FIG. 7

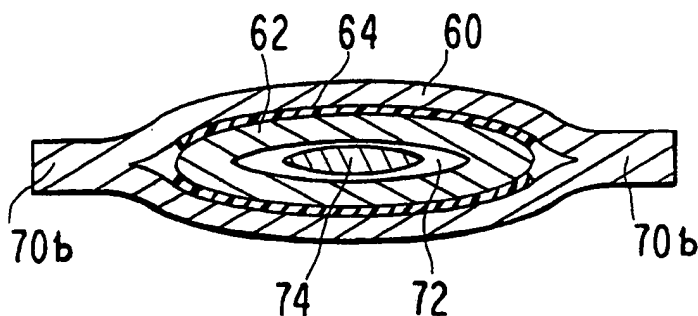


FIG. 8

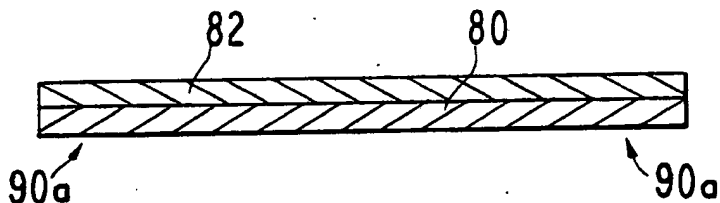


FIG. 9

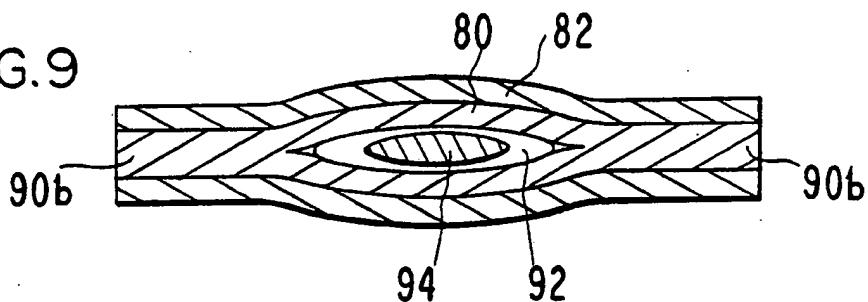


FIG. 10

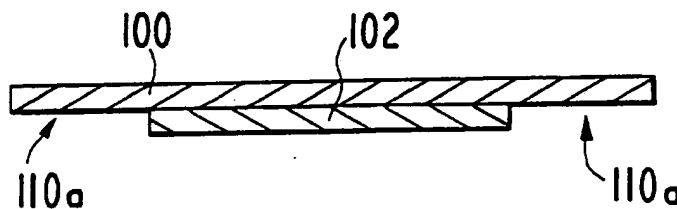


FIG. 11

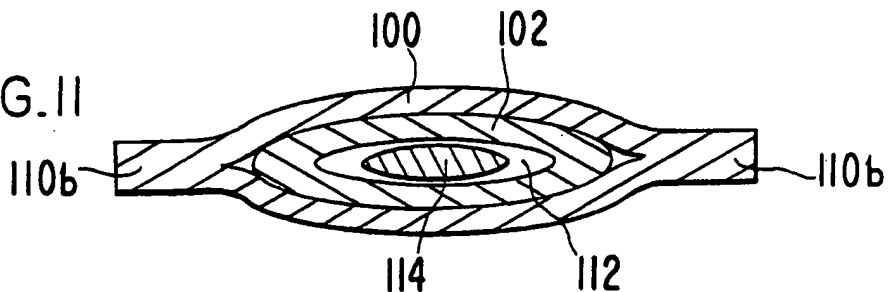
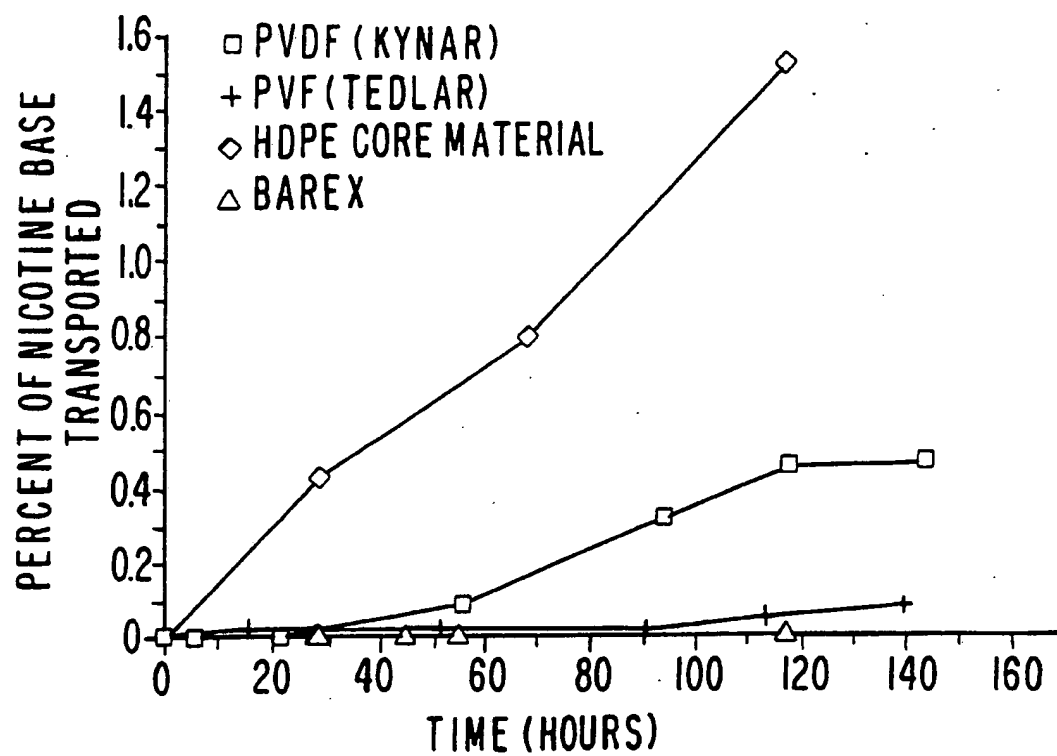


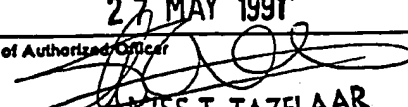
FIG.12



INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 90/07543

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) *		
According to International Patent Classification (IPC) or to both National Classification and IPC		
IPC ⁵ : B 32 B 27/30, B 32 B 15/08, B 32 B 27/10, B 32 B 27/36		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁷		
Classification System	Classification Symbols	
IPC ⁵ : B 32 B, A 61 M, C 08 L 9/00		
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸		
III. DOCUMENTS CONSIDERED TO BE RELEVANT⁹		
Category ¹⁰	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
A	EP, A2, 0 273 004 (CIBA-GEIGY AG) 29 June 1988 (29.06.88), see claims; column 9, lines 7-9. ---	1, 8, 16, 20
A	EP, B1, 0 075 486 (POLYSAR LIMITED) 17 August 1988 (17.08.88), see claims; page 3, lines 59-61. ---	1-4, 8-10, 16, 20-22
A	Derwent Accession No. 80-79 937 (WPI) & JP, A, 55/124 654 (NITTO ELECTRIC IND. KK) 26 September 1980 (26.09.80). -----	1, 4, 8, 20
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>* Special categories of cited documents: ¹⁰</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 45%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"Z" document member of the same patent family</p> </div> </div>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
08 April 1991 (08.04.91)	27 MAY 1991 ¹	
International Searching Authority	Signature of Authorized Officer	
EUROPEAN PATENT OFFICE	 MISS J. TAZELAAR	

ANHANG
zum internationalen Recherchen-
bericht über die internationale
Patentanmeldung Nr.

ANNEX
to the International Search
Report to the International Patent
Application No.

ANNEXE
au rapport de recherche inter-
national relatif à la demande de brevet
international n°

SA43908

PCT/US 90/07543

In diesem Anhang sind die Mitglieder
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This Annex lists the patent family
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cited in the above-mentioned inter-
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Im Recherchenbericht angeführtes Patentdokument Patent document cited in search report Document de brevet cité dans le rapport de recherche	Datum der Veröffentlichung Publication date Date de publication	Mitglied(er) der Patentfamilie Patent family member(s) Membre(s) de la famille de brevets	Datum der Veröffentlichung Publication date Date de publication
EP-A2- 273004	29-06-88	AU-A1-81454/87 DK-A0- 6069/87 DK-A - 6069/87 EP-A3- 273004 FI-A0- 875098 FI-A - 875098 IL-A0- 84498 JP-A2- 1085912 NO-A0- 874824 NO-A - 874824 PT-A - 86138 US-A - 4911707 ZA-A - 8708657 US-A - 4917676	26-05-88 19-11-87 21-05-88 13-07-88 18-11-87 21-05-88 29-04-88 30-03-89 19-11-87 24-05-88 01-12-87 27-03-90 29-06-88 17-04-90
EP-B1- 75486	17-08-88	AU-A1-88631/82 AU-B2- 557928 CA-A1- 1175989 DE-CO- 3278909 EP-A1- 75486 JP-A2-58074725 JP-B4- 2046055 US-A - 4433077	31-03-83 15-01-87 09-10-84 22-09-88 30-03-83 06-05-83 12-10-90 21-02-84